

IN THE CLAIMS:

1. (Currently amended) A method for producing a recombinant retroviral particle, said recombinant retroviral particle comprising an RNA sequence encoding an SDI-1 polypeptide or a functional fragment thereof, the method comprising:

(a) stably transfecting an isolated producer cell line with a retroviral vector comprising in 5' to 3' order:

(a) (1) a 5' LTR ~~region of the structure U3-R-U5;~~

(b) (2) an SDI-1 coding sequence encoding said SDI-1 polypeptide or functional fragment thereof, wherein said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation; and

(c) (3) a 3' LTR region comprising a ~~completely or partially deleted complete or partial~~ U3 deletion and an insertion in place thereof, wherein said insertion comprises ~~region, wherein into said deleted U3 region has been cloned~~ a polylinker sequence into which a regulatory element or a promoter has been cloned inserted; and

(b) producing said recombinant retroviral particle in said stably transfected isolated producer cell line,

and further wherein

(i) ~~said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation;~~

(ii) (i) ~~after upon~~ infection of a target cell by said recombinant retroviral particle, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter, resulting in~~ said SDI-1 coding sequence ~~becoming~~ becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and

(iii) (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

2. (Previously presented) The method of Claim 1 wherein the retroviral vector comprises a DNA sequence encoding SDI-1.

3. (Previously presented) The method of Claim 1, wherein the functional fragment comprises amino acids 1 to 71 of human SDI-1.

4. (Previously presented) The method of Claim 1, wherein the functional fragment comprises amino acids 42 to 58 of human SDI-1.

5-8. (Canceled).

9. (Previously presented) The method of Claim 2, wherein the DNA sequence encoding an SDI-1 polypeptide or a functional fragment thereof is under transcriptional control of a regulatory element selected from the group consisting of a target cell specific regulatory element, a target cell specific promoter, and an X-ray inducible promoter.

10. (Previously presented) The method of Claim 9 wherein the regulatory element is selected from the group consisting of a Whey Acidic Protein (WAP) regulatory element and a mouse mammary tumor virus (MMTV) regulatory element.

11. (Previously presented) The method of Claim 10 wherein the retroviral vector is pLXS-SDI1.

12. (Canceled).

13. (Currently amended) An isolated producer cell line stably transfected with a retroviral vector encoding an SDI-1 polypeptide or a functional fragment thereof, said retroviral vector comprising in 5' to 3' order:

- (a) ~~a 5' LTR region of the structure U3-R-U5;~~
- (b) a sequence encoding an SDI-1 polypeptide or a functional fragment thereof, wherein said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation; and
- (c) a 3' LTR region comprising a ~~completely or partially deleted~~ complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises ~~region, wherein into said deleted U3 region has been cloned~~ a polylinker sequence into which a regulatory element or a promoter has been cloned, inserted,

and further wherein

- ~~(i) — said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation:~~
- (ii) (i) after upon infection of a target cell by said a recombinant retroviral particle encoded by said retroviral vector, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter, resulting in~~ said SDI-1 coding sequence ~~becoming~~ becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and
- (iii) (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

14. (Currently amended) The isolated producer cell line of Claim 13, wherein the isolated producer cell[[s]] line is a human cell line.

15-18. (Canceled).

19. (Previously presented) A pharmaceutical composition comprising the isolated producer cell line of Claim 13 and a pharmaceutically acceptable carrier or diluent.

20-25. (Canceled).

26. (Currently amended) A method for introducing a DNA sequence encoding an SDI-1 polypeptide or a functional fragment thereof[[,]] into a human cell *in vitro*, the method comprising infecting the human cell with a retroviral particle produced by the isolated producer cell line of Claim 13.

27. (Currently amended) A method for treating a subject having a tumor or restenosis, the method comprising administering into said tumor or a site of restenosis of said subject ~~to the subject~~ a therapeutically effective amount of a recombinant retroviral particle produced by the isolated producer cell line of Claim 13 ~~at a site of the tumor or restenosis~~.

28-30. (Canceled).

31. (Currently amended) The method according to Claim 27 wherein the administering is by injection of the recombinant retroviral particle into said tumor or said site of restenosis of said subject ~~at a site of the tumor or restenosis.~~

32. (Canceled).

33. (Currently amended) A method for producing a recombinant retroviral particle, said recombinant retroviral particle comprising an RNA sequence encoding an SDI-1 polypeptide, the method comprising:

(a) stably transfecting an isolated producer cell line with a retroviral vector comprising in 5' to 3' order:

(a) (1) a 5' LTR ~~region of the structure U3-R-U5;~~

(b) (2) a coding sequence encoding the SDI-1 polypeptide, wherein said SDI-1 polypeptide inhibits cell proliferation; and

(c) (3) a 3' LTR region comprising a ~~completely or partially deleted complete or partial U3 deletion and an insertion in place thereof,~~ wherein said insertion comprises ~~region, wherein into said deleted U3 region has been cloned~~ a polylinker sequence into which a regulatory element or a promoter has been cloned; and inserted;

(b) producing said recombinant retroviral particle in said stably transfected isolated producer cell line,

and further wherein

(i) ~~said SDI-1 polypeptide inhibits cell proliferation;~~

(ii) (i) after upon infection of a target cell by said recombinant retroviral particle, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter, resulting in~~ said SDI-1 coding sequence ~~becoming~~ becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and

~~(iii)~~ (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

34-35. (Canceled).

36. (Previously presented) The method of Claim 33 wherein the regulatory element or promoter is selected from the group consisting of a target cell specific regulatory element, a target cell specific promoter, and an X-ray inducible promoter.

37. (Previously presented) The method of Claim 36 wherein the regulatory element is selected from the group consisting of a Whey Acidic Protein (WAP) regulatory element and a mouse mammary tumor virus (MMTV) regulatory element.

38. (Previously presented) The method of Claim 37 wherein the retroviral vector is pLXS-SDI1.

39. (Currently amended) An isolated producer cell line stably transfected with a retroviral vector encoding an SDI-1 polypeptide, said retroviral vector comprising in 5' to 3' order:

- (a) a 5' LTR ~~region of the structure U3-R-U5;~~
- (b) a sequence encoding an SDI-1 polypeptide, wherein said SDI-1 polypeptide inhibits cell proliferation; and
- (c) a 3' LTR region comprising a ~~completely or partially deleted~~ complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises region, ~~wherein into said deleted U3 region has been cloned a~~ polylinker sequence into which a regulatory element or a promoter has been ~~inserted~~ cloned,

and further wherein

- ~~(i) — said SDI-1 polypeptide inhibits cell proliferation;~~
- ~~(ii)~~ (i) after upon infection of a target cell by ~~said a~~ recombinant retroviral particle encoded by said retroviral vector, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter, resulting in said SDI-1 coding sequence becoming~~ becomes operatively linked to said regulatory element or promoter and said

regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and

~~(iii)~~ (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

40. (Previously presented) The isolated producer cell line of Claim 39, wherein the isolated producer cell line is a human cell line.

41-42. (Canceled).

43. (Previously presented) A method for introducing a DNA sequence encoding an SDI-1 polypeptide into a human cell *in vitro*, the method comprising infecting the human cell with a retroviral particle produced by the isolated producer cell line of Claim 39.

44. (Previously presented) A method for producing a recombinant retroviral particle, said particle comprising an RNA sequence encoding a polypeptide comprising amino acids 1 to 71 of human SDI-1, the method comprising stably transfecting an isolated producer cell line with a retroviral vector comprising a DNA sequence which encodes the polypeptide, wherein:

- (i) the polypeptide inhibits cell proliferation; and
- (ii) said producer cell comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

45. (Currently amended) An isolated producer cell line stably transfected with a retroviral vector encoding a polypeptide comprising amino acids 1-71 of human SDI-1, said retroviral vector comprising in 5' to 3' order:

- (a) a 5' LTR ~~region of the structure U3-R-U5;~~
- (b) a sequence encoding a polypeptide comprising amino acids 1-71 of human SDI-1, wherein said polypeptide comprising amino acids 1-71 of human SDI-1 inhibits cell proliferation; and
- (c) a 3' LTR region comprising a ~~completely or partially deleted~~ complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises ~~region, wherein into said deleted the~~ U3 ~~region has been~~

~~cloned~~ a polylinker sequence into which a regulatory element or a promoter has been ~~inserted~~ cloned,
and further wherein

~~(i)~~ ~~said polypeptide inhibits cell proliferation:~~

~~(ii)~~ (i) after infection of a target cell by ~~said~~ a recombinant retroviral particle encoded by said retroviral vector, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter, resulting in~~ said SDI-1 coding sequence ~~becoming~~ becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and

~~(iii)~~ (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

46-47. (Canceled).

48. (Previously presented) A method for introducing a DNA sequence encoding a polypeptide comprising amino acids 1-71 of human SDI-1 into a human cell *in vitro*, the method comprising infecting the human cell with a retroviral particle produced by the isolated producer cell line of Claim 45.

49. (Previously presented) A method for producing a recombinant retroviral particle, said particle comprising an RNA sequence encoding a polypeptide comprising amino acids 42 to 58 of human SDI-1, the method comprising stably transfecting an isolated producer cell line with a retroviral vector comprising a DNA sequence which encodes the polypeptide, wherein:

(i) the polypeptide inhibits cell proliferation; and

(ii) said producer cell comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

50. (Currently amended) An isolated producer cell line stably transfected with a retroviral vector encoding a polypeptide comprising amino acids 42-58 of human SDI-1, said retroviral vector comprising in 5' to 3' order:

- (a) a 5' LTR ~~region of the structure U3-R-U5;~~
- (b) a sequence encoding a polypeptide comprising amino acids 42-58 of human SDI-1, wherein said polypeptide comprising amino acids 42-58 of human SDI-1 inhibits cell proliferation; and
- (c) a 3' LTR region comprising a ~~completely or partially deleted~~ complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises ~~region,~~ wherein ~~into said deleted~~ the U3 ~~region has been~~ cloned a polylinker sequence into which a regulatory element or a promoter has been ~~inserted~~ cloned,

and further wherein

- (i) ~~said polypeptide inhibits cell proliferation;~~
- (ii) (i) ~~after~~ upon infection of a target cell by ~~said~~ a recombinant retroviral particle encoded by said retroviral vector, ~~said U3 of said 5' long terminal repeat region is replaced by said completely or partially deleted U3 region and said regulatory element or promoter,~~ resulting in said SDI-1 coding sequence ~~becoming~~ becomes operatively linked to said regulatory element or promoter and said regulatory element or promoter ~~regulating~~ regulates expression of said SDI-1 coding sequence in said target cell; and
- (iii) (ii) said isolated producer cell line comprises at least one DNA construct encoding a protein required for said retroviral vector to be packaged.

51-52. (Canceled).

53. (Previously presented) A method for introducing a DNA sequence encoding a polypeptide comprising amino acids 42-58 of human SDI-1 into a human cell *in vitro*, the method comprising infecting the human cell with a retroviral particle produced by the isolated producer cell line of Claim 50.

54. (Previously presented) A recombinant retroviral particle produced by the method of Claim 1.

55. (Previously presented) A pharmaceutical composition comprising the retroviral particle of Claim 54 and a pharmaceutically acceptable carrier or diluent.

56-64. (Canceled).

Please add the following new claims:

65. (New) A method for producing a recombinant retroviral particle, said particle comprising an RNA sequence encoding an SDI-1 polypeptide or a functional fragment thereof, the method comprising:

- (a) stably transfecting an isolated producer cell line with a retroviral vector comprising in 5' to 3' order:
 - (1) a 5' LTR;
 - (2) an SDI-1 coding sequence encoding said SDI-1 polypeptide or functional fragment thereof, wherein said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation; and
 - (3) a 3' LTR region comprising a complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises a regulatory element or a promoter; and
- (b) producing said recombinant retroviral particle in said stably transfected isolated producer cell line.

66. (New) An isolated producer cell line stably transfected with a retroviral vector encoding an SDI-1 polypeptide or a functional fragment thereof, the retroviral vector comprising in 5' to 3' order:

- (a) a 5' LTR;
- (b) a sequence encoding an SDI-1 polypeptide or a functional fragment thereof, wherein said SDI-1 polypeptide or functional fragment thereof inhibits cell proliferation; and
- (c) a 3' LTR region comprising a complete or partial U3 deletion and an insertion in place thereof, wherein said insertion comprises a regulatory element or a promoter.